



UNITED STATES PATENT AND TRADEMARK OFFICE

[Handwritten mark]

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,288	09/19/2003	Naheed Visram	12361-10US-1 JEL	1520

7590 09/13/2006

Louis Tessier
P.O. BOX 54029
CANADA, QC H3P3H4
CANADA

EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,288	VISRAM ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-28,30,31,53 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-28,30,31,53 and 55 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-4-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The action is **non-final**.

Claims 18-28, 30-31, 53 and 55 are pending. Claim 18 is the lone independent.

Shah et al. (6,565,562) is presented to show in a method analogous to Eggers' method, the use of a grounding pad as a return electrode, and hole creation in septal material as now claimed by the Applicant.

Claim Objections

Claim 53 is objected to because of the following informalities: the claim depends upon cancelled claim 52. Appropriate correction is required. The claim is examined as though it depends upon independent claim 18.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "auxiliary radiopaque marking" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 18-21, 24-28, 30, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (6,032,674) in view of Shah et al. (6,565,562).

Eggers et al. (6,032,674) discloses a method of creating channels/holes/cell lysis (col. 3:34-36) in cardiac septal material (**“heart tissue” - includes septal material – col. 1:59-60, also inherently includes the fossa ovalis**) in which channels are created by delivering RF (col. 12:55) energy/current into material (see figure 11) from active electrode (first sentence of the Abstract) with distal region (200, figure 11) softer than a proximal region (344, figure 11) introduced through the vasculature (see figure 11) using a dilator (340, figure 11) and guiding sheath (col. 5:50-55; again see figure 11) aided with fluoroscopy/radiopaque markers/depth marker (col. 4:59-64).

Eggers et al. is silent regarding a grounding pad as the return electrode as well as creating a channel through “septal material”. (Eggers does disclose that the return electrode need not be integral with the disclosed probe and therefore can be attached to a separate device (such as a grounding pad.) See col. 4:31-32, col. 5:55-57 and col. 10:28-30.

Shah discloses a channeling method analogous to Eggers in which a grounding pad (9) is used as a return electrode. Shah also discusses RF creation of a hole in the septal material ("atrial septum", col. 1:18-21 and col. 2:19-22).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Eggers in view of Shah by including into the Eggers method a grounding pad as disclosed by Shah the motivation being to permit monopolar energy application by using a well-known and tested structure (grounding pad element 9) as seen in Shah figure 1. It would further be obvious to use the Eggers method for creating a hole in septal material the motivation being to "improve intertribal communication" posited in Shah col. 2:22.

2. Claims 22-23 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (6,032,674) in view of Shah et al. (6,565,562) and further in view of Lesh et al. (6,650,923).

Eggers/Shah is silent regarding pressure sensing.

Lesh discloses in an analogous procedure a pressure sensor for measuring blood pressure in both atria (col. 9:4-10) subsequent to locating the fossa ovalis (col. 3:7-17) through radiopaque (col. 8:57-64, col. 7:27) staining (col. 4:29-33; col. 9:12-16 – after the puncture).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Eggers in view of Shah and further in view of Lesh by including into the Eggers method pressure sensing as disclosed by Lesh the motivation

Art Unit: 3739

being to permit measurement of blood pressure in order to determine location of the distal tip of the catheter (Lesh col. 9:4-10).

Response to Arguments

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

The prior 35 USC § 112 rejections are obviated through amendments/clarifying arguments.

Shah, in a method analogous and seamlessly combined with Eggers, clearly discloses creating a channel in septal material. This effectively counters the argument that Eggers does not disclose creating channels in *septal material*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

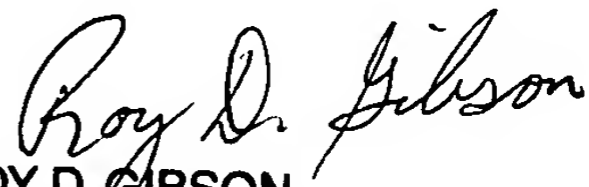
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos
September 1, 2006




ROY D. GIBSON
PRIMARY EXAMINER